

In the claims:

1. (previously amended) A biologically active extract comprising an extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus*, *Aframomum daneilli*; *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis*, wherein said extract is obtained using an organic solvent.

2. (withdrawn) A biologically active extract according to claim 1, wherein said extract is from *Aframomum aulocacarpus*.

3. (withdrawn) A biologically active extract according to claim 2, wherein said extract comprises a Labda-8(17), 12 diene-15,16-dial compound.

4. (withdrawn) A biologically active extract according to claim 1, wherein said extract is from *Aframomum daneilli*.

5. (withdrawn) A biologically active extract according to claim 4, wherein said extract comprises a Labda-8(17), 12 diene-15,16-dial compound.

6. (withdrawn) A biologically active extract according to claim 1, wherein said extract is from *Dracaena arborea*.

7. (withdrawn) A biologically active extract according to claim 6, wherein said extract comprises *Mannispirostan A*.

8. (withdrawn) A biologically active extract according to claim 1, wherein said extract is from *Eupatorium odoratum*.

9. (withdrawn) A biologically active extract according to claim 8, wherein said extract comprises Sakuranetin.

10. (withdrawn) A biologically active extract according to claim 1, wherein said extract is from *Glossocalyx brevipes*.

11. (original) A biologically active extract according to claim 1, wherein said extract is from *Napoleonaea imperialis*.

12. (original) A biologically active extract according to claim 1, wherein said extract is from at least one of roots, stem bark, leaves, fruits or seeds from said plant.

13. (withdrawn) A method of preparing a biologically active extract from at least one plant selected from the group

consisting of *Aframomum aulocacarpus*, *Aframomum daneilli*, *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis*, the method comprising:

selecting a solvent which dissolves or solubilizes a desired biologically active compound from said plant'

combining said solvent and said pulverized plant to extract said desired biologically active compound; and

removing said solvent from said extract of said desired biologically active compound.

14. (withdrawn) A method according to claim 13, wherein said plant comprises *Aframomum aulocacarpus*.

15. (withdrawn) A method according to claim 13, wherein said plant comprises *Aframomum daneilli*.

16. (withdrawn) A method according to claim 13, wherein said plant comprises *Dracaena arborea*.

17. (withdrawn) A method according to claim 13, wherein said plant comprises *Eupatorium odoratum*.

18. (withdrawn) A method according to claim 13, wherein said plant comprises *Glossocalyx brevipes*.

19. (withdrawn) A method according to claim 13, wherein said plant comprises *Napoleonaea imperialis*.

20 (withdrawn) A topical composition comprising a biologically active extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus*, *Aframomum daneilli*, *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis* in a topical carrier.

21. (withdrawn) An oral composition comprising a biologically active extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus*, *Aframomum daneilli*, *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis* in an oral carrier.

22. (withdrawn) An intravenous composition comprising a biologically active extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus*, *Aframomum daneilli*, *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis* in an intravenous carrier.

23. (withdrawn) A method of treating a fungal or protozoal disease in a mammal comprising applying a biologically active

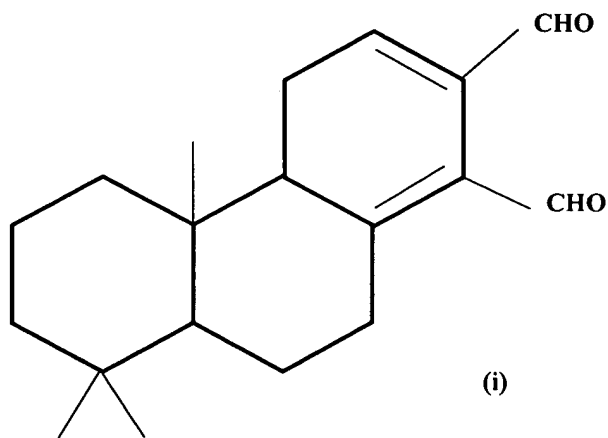
extract from at least one plant selected from the group consisting of *Aframomum aulocacarpus*, *Aframomum daneilli*, *Dracaena arborea*, *Eupatorium odoratum*, *Glossocalyx brevipes* and *Napoleonaea imperialis*.

24. (withdrawn) Method according to claim 23, comprising applying a topical composition containing said biologically active extract.

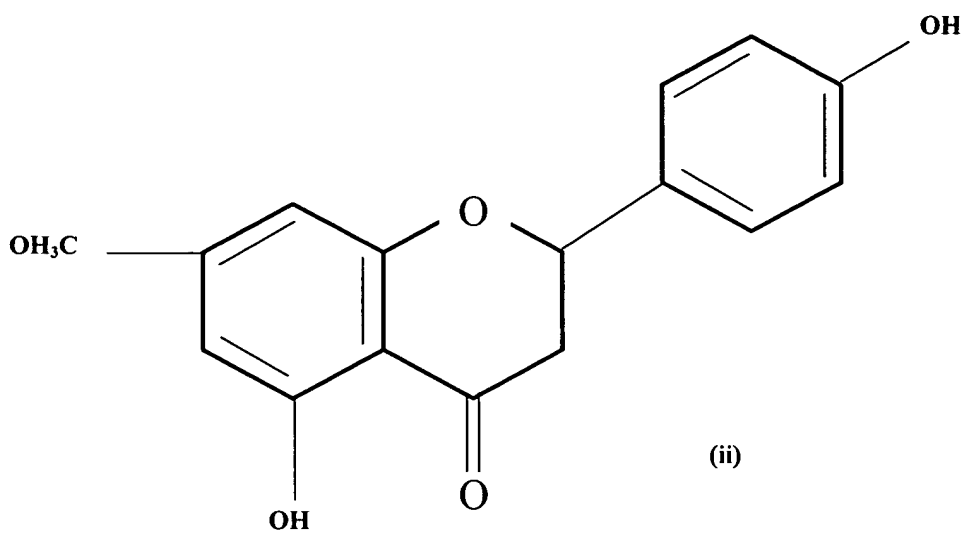
25. (withdrawn) Method according to claim 23, comprising ingesting an oral composition containing said biologically active extract.

26. (withdrawn) Method according to claim 23, comprising injecting an intravenous composition containing said biologically active extract.

27. (withdrawn) A compound comprising:

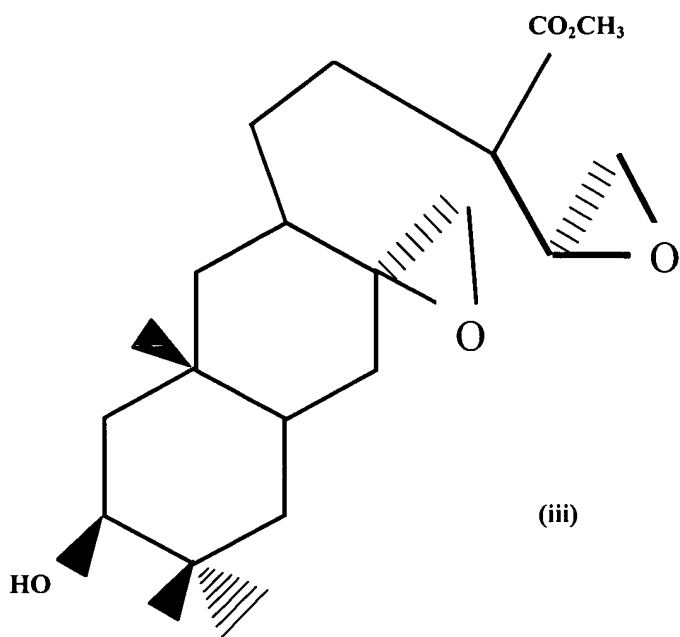


28. (withdrawn) A compound comprising:



$\text{C}71.3\%\text{H}6.3\%\text{O}22.4\%$

29. (withdrawn) A compound comprising:



30. (previously amended) A biologically active extract according to claim 1, wherein said solvent is selected from a group consisting of hexane, chloroform, ethyl acetate and methanol.

31. (previously amended) A biologically active extract according to claim 30, wherein said solvent is methanol.

32. (currently amended) A biologically active extract according to claim 30, wherein said solvent is ethyl acetate.

33. (withdrawn) A method for forming a biological extract of *Napoleonaea imperialis* including the steps of:

- (a) mixing powdered seeds of *Napoleonaea imperialis* with a solvent;
- (b) extracting said extract from said seeds; and
- (c) concentrating said extract to dryness.

34. (withdrawn) A method for forming a biological extract as recited in claim 33 wherein said solvent of said mixing step (a) is methanol.

35. (withdrawn) A method for forming a biological extract as recited in claim 33, wherein said solvent of said mixing step (a) is ethyl acetate.

36. (previously presented) A biologically active extract according to claim 11, wherein said extract is obtained from powdered seeds of *Napoleonaea imperialis*.

37. (previously presented) A biologically active extract according to claim 36, wherein said solvent is selected from a group consisting of hexane, chloroform, ethyl acetate and methanol.

38. (previously presented) A biologically active extract according to claim 37, wherein said solvent is methanol.

39. (currently amended) A biologically active extract according to claim 37, wherein said solvent is ethyl acetate ~~methanol~~.



## **RESPONSE**

1. The notice of abandonment of March 24, 2004, is acknowledged. The abandonment was unintentional for the reasons stated in the petition for revival. The amendment and response is pursuant to the examiner's office action of August 18, 2003.

2. The examiner's restriction is acknowledged. Applicants reserve the right to file a divisional application for the non-elected claims.

3. Please note that claim 32 has not been addressed in the August 18, 2003, office action. Claim 32 is part of the claims elected by applicants (see page 4 and 9 of applicants' preliminary amendment, filed July 11, 2003). Applicants respectfully request that the merits of claim 32 be addressed by the examiner in her next office action. In view of this omission, it is the applicants' position that any subsequent action by the examiner cannot be made final with respect to the rejection of the claims. To do so would preclude applicants the opportunity to address the examiner's rejections on the whole and individually with respect to claim 32.

3. Claim 39 has been amended to recite a limitation to overcome the examiner's objections.

4. Claims 1, 11, 12, 30 and 31 were rejected as being anticipated by Ekpendu, et al.

It is the examiner's position that Ekpendu, et al., teach methanol, hexane and ethyl acetate extracts of the root bark of *Napoleonaea imperialis* and that the teaching inherently includes seeds and powdered seeds of *Napoleonaea imperialis*. Thus, the examiner concludes that Ekpendu, et al., anticipate the applicants' claim by disclosing a method of extracting components from *N. imperialis*.

The examiner's rejection is respectfully traversed.

As stated in the amendment and response of July 11, 2003, Ekpendu, et al., disclose hydrolyzed hexane, ethyl acetate and methanolic compounds (see Ekpendu, et al., page 76) that begin with the crude extract obtained from the root bark of *N. imperialis*. Ekpendu, et al., are not directed to determining biological activity. Rather, Ekpendu, et al., are directed to identifying compounds present in known traditional medicinal plants. To reiterate, hydrolysis is unnecessary and detrimental to applicants' invention as the biological efficacy of *N. imperialis* against pathogens would be severely compromised.

The examiner's position that Ekpendu's teaching is inherent to the applicants' disclosure and claimed disclosure that seeds

and powdered seed extracts of *N. imperialis* exhibit specific biological activity is without merit.

Please note that Dr. Okunji, the first named inventor of the present application, is familiar with the researchers involved with the Ekpendu, et al., publication. Dr. Okunji's work on leishmania is the product of his PhD dissertation, i.e. the use of seeds vs. that of other plant parts such as extracts. To illustrate the above points, his research interest on the genus *Napoleonaea* started as far back as 1983 when he screened this plant for molluscicidal activity. His Ph.D. dissertation in 1987 entitled "Molluscicidal and Antifungal Properties of Some Nigerian Medicinal Plants" identified *Napoleonaea vogeli* auct. (Fam. Lecythidaceae) Synonyms *Napoleonaea imperialis* P. Beauv. ([http://mobot.mobot.org/cgi-bin/search\\_vast](http://mobot.mobot.org/cgi-bin/search_vast)) as potential plant molluscicides. Further screening of this plant for antileishmanial activity in 1993 identified *Napoleonaea imperialis* seeds as having a promising antileishmanial activity. Bioassay guided-chromatographic fractionation of *Napoleonaea imperialis* seeds yielded imperialisides (A-C).

Dr. Ekpendu's group studied "haxane (sic), ethyl acetate and methanol extracts of *Napoleonaea imperialis*, obtained from the root bark, not the extracts from the seeds themselves. As established in the present patent application, the seeds were chosen to obtain biologically active extracts showing

antileishmanial activity. Thus, Ekpendu, et al., cannot anticipate or make obvious that one of ordinary skill in the art would have known that hydrolyzed extracts of root bark would show the type of biological activity disclosed and claimed by applicants. To do so would require Ekpendu, et al., to utilize the teachings of this patent application.

5. Claims 1, 11, 12, 30, 31, and 36-39 were rejected as being anticipated by Kapundu, et al.

The examiner contends that Kapundu, et al., teach a methanol extract from powdered seeds of *Napoleonaea imperialis*. While the examiner notes that Kapundu, et al., fail to teach biologically activity of *N. imperialis* as taught by applicants, the differences between Kapundu, et al., and the applicants' invention are inherently taught by Kapundu, et al.

The examiner's position is respectfully traversed.

As discussed in the applicants' preliminary amendment and response of July 11, 2003, Kapundu, et al., identify a prosapogenin structure after the seed saponin of *N. imperialis* is hydrolyzed. The methalonic extract, as disclosed by Kapundu, et al., is a first step in a two-step process for identifying the structure. Applicants disclose and claim a methanol extract obtained from the powdered seeds of *N. imperialis* for testing efficacy against Leishmania and other pathogens. As taught by

applicants, the methanol and ethanol seed fractions have been shown to have direct inhibitory effects against the growth of Leishmania promastigotes. The extract is obtained without hydrolysis. To note, Kapundu, et al., is further directed to compound identification, thus necessitating the hydrolysis step. Based on these unobvious distinctions between the applicants' invention and the Kapundu, et al., reference, it is unclear how the examiner establishes an argument for inherency. Furthermore, the applicants of the present invention are aware of the contributions of the Kapundu, et al., group, as the reference was cited in Dr. Okunji's doctoral thesis (cited above) as a preliminary evidence of the use of African plants in traditional medicine.

Due to extreme hardships on the part of the applicants, we are unable to supply the office with 132 affidavits from the Ekpendu, et al., group. However, if necessary, applicants will provide the office with a 132 affidavit from Dr. Okunji attesting to the subject matter of Dr. Okunji's dissertation and distinguishing the applicants' present invention from that of the prior art.

For the reasons given above, it is the applicants' position that the claims overcome the examiner's rejection. Early allowance of the claims is respectfully solicited.